

REMARKS

Applicant thanks Examiner Rogers for his time and consideration of the present application during the telephonic interview of February 21, 2008 with the undersigned.

During the interview proposed amendments to the claims were discussed, such as claiming the composition and kit separately. The failings of the prior art were discussed. For example, the composition of GARIBALDI requires both adhesives and magnetic materials, and MARINOVIC and PORTER fail to teach polyurethane polymers dissolved in a solvent.

Claims 32, 36, 40, 41, 43, 45, 46, and 50-57 are amended.

Claims 59-65 are new.

Support for the amended and new claims may be found, e.g., in the paragraph bridging pages 3 and 4, item 6 of page 11, item 15 of page 13, and the last paragraph of page 7 of the specification.

Claims 33-35, 47-49 and 58 are cancelled.

Claims 32, 36-46, 50-57, and 59-65 remain pending.

The Official Action rejects claims 32-36, 40-41, 43, 45-50, 54-55 and 57-58 under 35 USC §102(b) as anticipated by GARIBALDI et al. U.S. 6,296,604 (GARIBALDI). This rejection is respectfully traversed.

The position of the Official Action is that the adhesive of GARIBALDI would not materially affect the claimed

composition properties if used in lower concentrations, and that paramagnetic materials are not excluded by the claimed invention.

However, GARIBALDI cannot anticipate the claimed invention for at least two reasons:

I. GARIBALDI requires adhesion to the artery walls.

GARIBALDI discloses, "A minimum percentage of adhesive is required to insure enough cohesion of the embolic plug to prevent its breaking or flaking in the presence of high velocity blood flow, and to provide sufficient adhesion of the plug to the wall of the artery." (Emphasis added.) See, e.g., the paragraph bridging columns 12 and 13 of GARIBALDI.

Independent claims 32, 46, and 59 recite: the composition does not stick to the blood vessel walls. Additionally, the independent claims recite the compositions "consist essentially of" a polymer and solvent or solvent mixture. Thus, an adhesive that would cause the composition to stick to blood vessel walls is excluded from the claimed invention, as it would affect the basic and novel characteristics of the claimed invention.

II. GARIBALDI requires a magnetic material.

GARIBALDI requires a magnetic material, which may also provide characteristics similar to a paramagnetic material.

GARIBALDI describes a paramagnetic material as "one that is attracted by a magnetic field, but does not retain magnetism once the magnetic field is removed." (Emphasis added.)

See, e.g., column 4, lines 15-18. A paramagnetic material "such as barium or tantalum may be added to render the composition radiopaque and thus visible under fluoroscopy". See, e.g., column 4, lines 13-15 and column 13, lines 5-7. However, specific magnetic material "such as pure iron, carbonyl iron, coated iron, and coated carbonyl iron (preferably pure iron) is used to provide both radiopacity and magnetic responsiveness". (Emphasis added.) See, e.g., column 4, lines 20-23 and column 13, lines 5-12, and the claims.

As evidenced by GARIBALDI, a paramagnetic material does not retain magnetism whereas a magnetic material does retain its magnetism. The claimed invention does not exclude contrast materials, such as paramagnetic materials, as they are used to visually follow the composition, and not affect the basic and novel characteristics. However, a magnetic material is excluded from the claimed invention, as a magnetic material would permanently affect the basic and novel characteristics by causing the composition to be magnetized.

Therefore, GARIBALDI cannot anticipate independent claims 32, 46, and 59, and dependent claims 36-45, 50-57, and 60-65, and withdrawal of the rejection is respectfully requested.

Claims 32-34, 37-42, 44, 46-48 and 51-56 stand rejected under 35 USC §102(b) as being anticipated by MARINOVIC EP 0 280 451(MARINOVIC). This rejection is respectfully traversed.

The position of the Official Action is that the polyether urethane urea polymer of MARINOVIC meets the recitation of "polyurethane" in the claimed invention, and that the method of how the polymer precipitates is not considered for the claimed invention. However, MARINOVIC cannot anticipate the claimed invention for at least three reasons:

I. Neither the pre-polymer nor the polymer of MARINOVIC is the claimed polymer.

MARINOVIC discloses forming a polyetherurethane urea polymer from a pre-polymer. See, e.g., the reaction described on page 4 of MARINOVIC.

The prepolymer is a polyether diurethane. That is, the prepolymer contains only two urethane groups, and, thus, cannot be considered a polyurethane. See, e.g., page 6, line 41 of MARINOVIC: "A. POLYETHERURETHANE-DIISOCYANATE PREPOLYMERS", or, more precisely, "polyetherdiurethane-diisocyanate prepolymers".

The polymer is a polyetherurethane urea polymer. The polyetherdiurethane diisocyanate prepolymer is reacted with a diamine-type of "chain extender"  $[-NHCONHCH_2CH_2NH-]$  so that the polyether type core is linked together with urea-type groups to form the final "polyetherurethane urea" polymer:  $OCN-Z-NHCOO-(polyether)-OCONH-Z-NCO$ . MARINOVIC further discloses, "In principle, all free NCO groups are converted to urea (or related groups depending upon the exact nature of the chain extending compound) in the formation and hardening of the space filling

adhesive." See, e.g. page 6, lines 9-10. Thus, the resulting polymer comprises many ether polymers and two urethane terminal groups, i.e., the polymer is a diisocyanate-type compound having a polyether core.

While the Official Action simply refers to [-NHCOO-(polyether)-OCONH-], reference to this portion alone is misleading. This portion of the polymer would suggest that some polyether parts are linked by urethane groups in the polymer, which is not accurate. Instead, the two urethane groups in questions are each part of a terminal group, or a polymer chain-closing group at each end of the polymer.

Thus, neither the prepolymer nor the polymer of MARINOVIC meets the recitation of a polyurethane polymer as claimed in independent claims 32, 46 and 59.

II. Neither the pre-polymer nor the polymer of MARINOVIC has the same characteristic as the claimed polymer.

The ability of a polymer to dissolve in a particular solvent and solidify absent the solvent does distinguish the claimed invention from MARINOVIC.

For example, the prepolymer of MARINOVIC does not have the ability to dissolve in a solvent and solidify upon removal of the solvent. Indeed, the prepolymer is a liquid that is hardened *in situ*. As discussed above, the prepolymer requires diamine type chain extender compounds to solidify. Accordingly, the liquid prepolymer is not dissolved in a solvent as recited in

claims 32 and 46, nor is it able to be dissolved in solvent and solidified upon removal of the solvent as recited in claim 59.

As to the polymer, the polymer is formed by cross-linking or hardening the pre-polymer, as discussed above. Accordingly, the hardened polymer is not dissolved in solvent as recited in claims 32 and 46, nor is it able to be dissolved in solvent and solidified upon removal of the solvent as recited in claim 59.

III. The MARINOVIC polymer is an adhesive.

The purpose of MARINOVIC is to prepare a polymer that serves as a tissue adhesive.

Independent claims 32, 46, and 59 recite: the composition does not stick to the blood vessel walls. Additionally, the independent claims recite the compositions "consist essentially of" a polymer and solvent or solvent mixture. Accordingly, the tissue adhesive is contrary to the claimed invention.

In view of the above, MARINOVIC cannot anticipate independent claims 32, 46, and 59, and dependent claims 36-45, 50-57, and 60-65.

Therefore, withdrawal of the rejection is respectfully requested.

Claims 32-37, 39, 43-51, 53 and 56-58 are rejected under 35 USC §102(e) as being anticipated by PORTER US

20002/0165583 (PORTER). This rejection is respectfully traversed.

The position of the Official Action is that the prepolymer forms a polyurethane in situ when delivered to the vascular site, and that a flush stream of solvent may be used to precipitate the polymer. Moreover, the position of the Official Action is that the compositions are the same scope as the claimed invention.

However, PORTER cannot anticipate the claimed invention, as PORTER fails to disclose a polyurethane polymer dissolved in a solvent as recited in claims 32 and 46, or capable of dissolution in a solvent and capable of solidifying upon separation from the solvent as recited in claim 59.

For example, as to the discussion in paragraph 59 cited by the Official Action, PORTER discloses foaming with a polyurethane prepolymer and crosslinking in situ upon mixing with water, not ethanol as stated in the Official Action.

Polymer solutions and solvents similar to those claimed in the dependent claims of the present invention, e.g., DMSO and ethanol, are separately discussed in paragraphs 88 and 90 of PORTER. However, these paragraphs refer to a special embodiment, e.g., "speeding up" of the precipitation by use of a nozzle. There is no discussion relative to polyurethane polymers, or soluble polyurethane polymers with respect to this embodiment.

Indeed, the polyurethane polymers disclosed by PORTER are limited to solid materials, i.e., in situ polymerized from prepolymers, preferably with strong cross-linking, e.g., as explained in paragraphs 59-60. The precipitation of the polymer may also be carried out by light or heat activation. See, e.g., paragraphs 46, 50, and 66. However, there is no teaching of dissolving polyurethane polymers. Accordingly, PORTER fails to disclose polyurethane polymers dissolved, or dissolvable, in a solvent, and solidifying the polyurethane polymer upon removal of the solvent.

Thus, in order to even approach the claimed invention one would have been forced to pick and choose a specific polymer and solvent for dissolving the polymer without any guidance from PORTER.

As the Court of Customs and Patent Appeals found in *In re Arkley*, 455 F.2d 586, 587, 172 USPQ 524, 526 (CCPA 1972):

"Such picking and choosing may be entirely proper in the making of the 103, obviousness rejection, where the applicant must be afforded an opportunity to rebut with objective evidence in inference of obviousness which may arise from the similarity of the subject matter which it claims to the prior art, but it has no place in the making of a 102, anticipation rejection." *Arkley*, 455 F.2d at 587-88, 172 USPQ at 526.

Therefore, PORTER cannot anticipate claims 32, 46, and 59, and dependent claims 36-45, 50-57, and 60-65, and withdrawal of the rejection is respectfully requested.



Claims 32-58 are rejected under 35 USC §103(a) as being unpatentable over GARIBALDI in view of MARINOVIC. This rejection is respectfully traversed.

GARIBALDI is offered for the reasons discussed above.

MARINOVIC is offered for the reasons discussed above, and particular for teaching particular polyurethanes.

However, in view of the discussion with respect to the anticipation rejection, GARIBALDI teaches away from the compositions of independent claims 32, 46, and 59, which do not stick the blood vessel walls and do not remain magnetized. MARINOVIC cannot remedy the shortcomings of GARIBALDI for reference purposes, as MARINOVIC requires adhesions to tissue, and fails to teach the a polyurethane polymer.

Therefore, the proposed combination cannot render obvious the claimed invention of claims 32, 46, and 59, and dependent claims 36-45, 50-57, and 60-65, and withdrawal of the rejection is respectfully requested.

Claims 32-58 are rejected under 35 USC §103(a) as being unpatentable over PORTER. This rejection is respectfully traversed.

As discussed above with respect to the anticipation rejection, there is no teaching in PORTER of polyurethane polymer dissolved in a solvent, as recited in claims 32 and 46, or a polyurethane polymer capable of being dissolved and re-solidified from a solvent as recited in independent claim 59. At best,

PORTER is limited to the precipitation of a polyurethane polymer from a prepolymer with the addition of a solvent. Accordingly, to even approach the claimed invention one would have been forced to pick a polyurethane polymer and a solvent for dissolving the polymer without any guidance from PORTER.

Therefore, the proposed combination cannot render obvious the claimed invention of claims 32, 46, and 59, and dependent claims 36-45, 50-57, and 60-65, and withdrawal of the rejection is respectfully requested.

In view of the amendment to the claims and the foregoing remarks, the present application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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